

National Security Assessment (Beijing) Medical Research Institute Co., LTD.

170121340472

Test Report

Acceptance Number: 2017/GJ-X-011

Sample name: Tianrun medical sterilization roll pouch

Sample quantity: 4 rolls

Sample size/model 200 m *150 mm

Sample color/properties White transparent paper plastic pouch

Sample receiving date: February 24, 2017

Production date/lot number 17.1.11/1701058

Test completion date 2019.04.08

Production company: Anhui Tianrun Medical Packaging Materials Co., LTD.

安徽天润医用新材料有限公司
ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD

Entrusted company: Anhui Tianrun Medical Packaging Materials Co., LTD.

Address: No. 2, Yingdeli Industrial Park, Wuzui Section, 206 National Road, Daqiao Development Zone, Yixiu District, Anqing City, Anhui Province

"Disinfection technical specifications" (2002 edition) 2.1.7.1, 2.1.7.2, 2.1.7.4, 2.1.7.5, 2.1.7.7 and 2.1.6.3

Entrusted by Anhui Tianrun Medical Packaging Materials Co., LTD.; The stability of Tianrun medical sterilization pouch has been tested for 24 months (since 2017, it has been evaluated by the National Inspection And Safety Inspection (Beijing & GT; It will be stored in The Institute of Medical Sciences Co., LTD for testing after February 14, 2019 at normal temperature and pressure), and the test results are reported as follows

Detection Conclusions:

1. General inspection: The indication package of Tianrun brand medical disaster bacteria should be stored for 24 months under normal temperature and pressure under sunlight.

The pouch is free from holes, cracks, tears, creases or local additions or thinness that may impair its function. Comply with the requirements of "Disinfection Technical Specification" (2002 annual edition) 2.1.7.1.1.

2. Quality measurement: The average weight per square meter of tianrun brand medical sterilization pouch stored at room temperature and pressure for 24 months is 67.93g, which meets the requirements of "Disinfection Technical Specification" (2002 edition) 2.1.7.1.2.

3. Penetration performance of sterilization factors: the biological indicators in tianrun medical sterilization indication package stored for 24 months at room temperature and pressure grow sterile after sterilization at 121°C for 30 min and 134°C for 4 min; At the temperature of 54°C, relative humidity of 60%, ethylene oxide gas concentration of 600 mg/L under the conditions of sterilization for 60 min, stored for 24 months at room temperature and pressure biological indicators in the tianrun brand medical sterilization indicator bag after sterilization are sterile growth to meet the sterilization standards. Comply with the requirements of "Disinfection Technical Specification" (2002 edition) 2.1.7.2.